

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

		DATA MATRIX			
Date May 17, 2011			EPA Reg No./File Symbol 43813-2		Page / of / 8
, ppindant or regionality of the control of the con		Product Fungaflor Technical			
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identity & composition	40478201	Jansen Pharmaceutica	own	
830.1550	Product identity & composition	42793802	Janssen Pharmaceutica	own	
330.1550	Product identity & composition	43016801	Janssen Pharmaceutica	own	
830.1600	Description of materials	40478201	Janssen Pharmaceutica	own	
330.1600	Description of materials	41595901	Janssen Pharmaceutica	own	
830.1600	Description of materials	41545101	Janssen Pharmaceutica	own	
330.1600	Description of materials	42403101	Janssen Pharmaceutica	own	
330.1620	Description of production process	40478201	Janssen Pharmaceutica	own	
330.1620	Description of production process	41595901	Janssen Pharmaceutica	own	
330.1620	Description of production process	41545101	Janssen Pharmaceutica	own	
330.1620	Description of production process	42403101	Janssen Pharmaceutica	own	
330.1670	Discussion of formation of impurities	40478201	Janssen Pharmaceutica	JWN	
330.1670	Discussion of formation of impurities	43223001	Janssen Pharmaceutica	own	
330.1700	Preliminary analysis	41889801	Janssen Pharmaceutica	own	
330.1750	Certified limits	41889801	Janssen Pharmaceutica	o\-'n	
Signature Milliam R	Loodwine		Name and Title William R. Goodwine, Director, Regulatory	Affairs	Date May 17, 2011



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		Product Fungaflor Technical			
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800	Enforcement analytical method	41889801	Jansen Pharmaceutica	own	
830.1800	Enforcement analytical method	42793801	Janssen Pharmaceutica	own	
830.6302	Color	41606106	Janssen Pharmaceutica	own	
830.6303	Physical state	41606106	Janssen Pharmaceutica	own	
830.6304	Odor	41606106	Janssen Pharmaceutica	own	
830.6313	Stability to temperatures, metals & metal ions	41606106	Janssen Pharmaceutica	own	
830.6313	Stability to temperatures, metals & metal ions	42793802	Janssen Pharmaceutica	own	
330.7000	pH	41606106	Janssen Pharmaceutica	own	
330.7200	Melting point	41606106	Janssen Pharmaceutica	own	
330.7300	Density/relative density/bulk density	41606106	Janssen Pharmaceutica	own	
330.7370	Dissociation constants in water	41606106	Janssen Pharmaceutica	own	
830.7550	Partition coefficient (n-octanol/water) - shake flask	41606106	Janssen Pharmaceutica	cwn	
330.7840	Water solubility	41606106	Janssen Pharmaceutica	own	
330.7840	Water solubility	42793802	Janssen Pharmaceutica	OWil	
30.7950	Vapor pressure	41606106	Janssen Pharmaceutica	OW/n	
Signature William R. L	Cooderine		Name and Title William R. Goodwine, Director, Regulatory Af	fairs	Date way 17, 2011



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Applicant's/Registrant's Name & Ad	Applicant's/Registrant's Name & Address		Product		
Janssen PMP, a Division of Jansse	en Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusvill	e, NJ 08560-0200	Fungaflor Technical		
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1750	Certification of Limits	42793801	Jansen Pharmaceutica	own	
830.1620	Description of production process	43223001	Janssen Pharmaceutica	own	
830.6302	Color	46713101	Janssen Pharmaceutica	own	
830.6303	Physical state	46713101	Janssen Pharmaceutica	own	
830.6304	Odor	46713101	Janssen Pharmaceutica	own	
830.6313	Stability to temperatures, metals & metal ions	46713101	Janssen Pharmaceutica	own	
830.6317 / 6320	Storage Stability / Corrosion Characteristics	46713102	Janssen Pharmaceutica	own	
830.7000	рH	46713101	Janssen Pharmaceutica	own	
830.7200	Melting point	46713101	Janssen Pharmaceutica	own	
830.7300	Density/relative density/bulk density	46713101	Janssen Pharmaceutica	own	
830.7370	Dissociation constants in water	46713101	Janssen Pharmaceutica	own	
830.7550	Partition coefficient (n-octanol/water) - shake flask	46713101	Janssen Pharmaceutica	own	
830.7840	Water solubility	46713101	Janssen Pharmaceutica	own	
830.7050	UV/Visible Absorption	45822501	Janssen Pharmaceutica	own	
830.7950	Vapor pressure	46725101	Janssen Pharmaceutica	ov/n	
Signature	11		Name and Title		Date
William R.	William R. Lloodwine		William R. Goodwine, Director, Regulatory Affairs		May 17, 2011

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		tusville, NJ 08560	Product FUNGAFLOR Technical		
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explodability	41606106	Janssen Pharmaceutica	Own	
830.6317	Storage Stability	41606106	Janssen Pharmaceutica	Own	
830.6320	Corrosion Characteristics	42012001	Janssen Pharmaceutica	Own	
830.1550	Product ID & Composition	42403101	Janssen Pharmaceutica	Own	
830.1650	Discussion of formation of impurities	43016801	Janssen Pharmaceutica	Own	
Signature William R. Mordune			Name and Title William R. Goodwine, Director, Regulatory A	Affairs	Date May 17, 2011



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Date May 17, 2011			EPA Reg No./File Symbol 43813-2		Page 5 of 1 8	
Applicant's/Registrant's Name & Address Janssen PMP, a Division of Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, NJ 08560-0200		NJ 08560-0200	Product Fungaflor Technical			
Ingredient Imazalil						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
81-1	Acute oral toxicity - rat (R23979/15)	00031596	Janssen Pharmaceutica	own	R23979/R27180	
81-2	Acute dermal toxicity - rabbit (2344)	41606104	Janssen Pharmaceutica	own	R23979	
81-3	Acute inhalation toxicity - rat (v83.308/230831)	00152439	Janssen Pharmaceutica	own	R23979	
81-3	Acute inhalation toxicity - rat (v83.308/230831-addenda)	41889802	Janssen Pharmaceutica	own		
31-3	Acute inhalation toxicity - rat (R23979/L7-supplement)	42603401	Janssen Pharmaceutica	own		
81-4	Primary eye irritation - rabbit (2253)	41606105	Janssen Pharmaceutica	own	R23979	
81-5	Primary dermal irritation (1864)	41328801	Janssen Pharmaceutica	own	R23979	
31-6	Dermal sensitization (2417)	41718701	Janssen Pharmaceutica	own	R23979	
31-6	Dermal sensitization (5337)	44512401	Janssen Pharmaceutica	own	R23979	
81-1	Acute oral toxicity - rat	46713104	Janssen Pharmaceutica	own		
31-3	Acute inhalation toxicity	46713105	Janssen Pharmaceutica	own		
81-5	Primary dermal irritation	46804501	Janssen Pharmaceutica	∩WI		
31-8	Acute Neurotoxicity	46820201	Janssen Pharmaceutica	own		
31-8	Acute Neurotoxicity	46820202	Janssen Pharmaceutica	ov.'n		
Signature William R.,			Name and Title		Date	
William R.	L'oodwine		William R. Goodwine, Director, Regulatory Af	fairs	Mεy 17, 2011	



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		NJ 08560-0200	Product O Fungaflor Technical		
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
82-1	90-day feeding study-dog (1899)	41328802	Janssen Pharmaceutica	own	
82-1	90-day feeding study - rat (3514-final)	43965704	Janssen Pharmaceutica	own	
82-1	90-day feeding study - rat (3672)	43965705	Janssen Pharmaceutica	own	
82-1	90-day feeding study - rat (V83.186/220555 - 6 mo.)	00162411	Janssen Pharmaceutica	own	
32-1	90-day feeding study - rat (V84.140/220555 - 18 mo.)	00162412	Janssen Pharmaceutica	own	
82-1	90-day feeding study - rat (3514-interim)	43735005	Jansen Pharmaceutica	own	
82-1	90-day feeding study - rat (3514-interim for FK1960)	43735006	Jansen Pharmaceutica	own	
32-2	21-day dermal-rabbit (2418)	42085201	Janssen Pharmaceutica	own	
32-2	21-day dermal-rabbit (2418-supplement)	43016802	Janssen Pharmaceutica	own	
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Signature William R. Moodwine		Name and Title William. R. Goodwine, Director, Regulatory Affairs		Date May 17, 2011	



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Applicant's/Registrant's Name & Address Janssen PMP, a Division of Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, NJ		IJ 08560-0200	Product 60-0200 Fungaflor Technical		
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-5	Combined Chronic/Cancer- rat (3817, final+addenda 1-7)	44858001	Janssen Pharmaceutica	own	
83-5	Combined Chronic/Cancer- rat (3817, interim)	44319901	Janssen Pharmaceutica	own	
83-1	Chronic feeding - rat (V84.140/220555, 18 mo.)	00162412	Janssen Pharmaceutica	own	
83-1	Chronic feeding - dog (1899)	41328802	Janssen Pharmaceutica	own	
83-5	Combined Chronic/Cancer- rat (AGR581/V85.153, adden	41558501	Janssen Pharmaceutica	own	
83-5	Combined Chronic/Cancer- rat (AGR581, Janssen reply)	43735004	Janssen Pharmaceutica	own	
83-5	Combined Chronic/Cancer- rat (3817, addenda 8)	44951001	Janssen Pharmaceutica	own	
83-5	Combined Chronic/Cancer- rat (AGR581/V85.155,final)	00162413	Janssen Pharmaceutica	own	
83-5	Combined Chronic/Cancer- rat (3817, addenda 9 [4032])	44951002	Janssen Pharmaceutica	own	
33-2	Oncogenicity study - mouse (2194, interim)	42890301	Janssen Pharmaceutica	own	
33-2	Oncogencity study - mouse (2194, final)	42972001	Janssen Pharmaceutica	owr	
33-2	Oncogenicity study - mouse (2194, supplement 1)	43242401	Janssen Pharmaceutica	∪\/I₁	1
33-2	Oncogenicity study - mouse (2194, supplement 2)	43735002	Janssen Pharmaceutica	own	
33-2	Oncogenicity study - mouse (2194, supplement 3)	44178501	Janssen Pharmaceutica	own	
33-2					
Signature William R. Lloodewine			Name and Title William. R. Goodwine, Director, Regulatory Affa	airs	Ը ե ն May 17, 2011



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Ingredient Imazalil	The manual state of the manual state of the	0,110 00000 0200	r unganor resumed		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-3	Developmental toxicity - rat (2003, 88-05)	41026603	Jansen Pharmaceutica	own	R27180
83-3	Developmental toxicity - rabbit (2615)	42593601	Janssen Pharmaceutica	own	R27180
83-3	Developmental toxicity - rabbit (2615, supplement)	43154201	Janssen Pharmaceutica	own	R27180
83-3	Developmental toxicity - rabbit (1482)	00162406	Janssen Pharmaceutica	own	R18531
83-3	Developmental toxicity - rabbit (1086)	00162408	Janssen Pharmaceutica	own	R18531
83-3	Developmental toxicity - mouse (745, 85-02)	00146151	Janssen Pharmaceutica	own	R27180
83-3	Developmental toxicity - mouse (2712)	44567802	Janssen Pharmceutica	own	R27180
83-3	Developmental toxicity - mouse (2374, 90-06)	44578201	Janssen Pharmceutica	own	R27180
33-3	Developmental toxicity - mouse (787 , 86-07)	44567803	Janssen Pharmaceutica	own	R27180
83-4	Reproduction, 3 generation (736)	41026604	Janssen Pharmaceutica	own	R25979
83-4	Reproduction, 2 generation (2337)	42570701	Janssen Pharmaceutica	owr	R23979
83-4	Reproduction, 2 generation (2337, supplement)	42949402	Janssen Pharmaceutica	JWh	R23979
Signature	Localwine		Name and Title		Patc
William K.	Dooduine		William. R. Goodwine, Director, Regulatory A	Affairs	May 17, 2011



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Janssen PMP, a Division of Jansse	en Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, N	J 08560-0200	Fungaflor Technical			
Ingredient Imazalil						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
34-2	Gene mutation (Ames - 1999)	40729301	Janssen Pharmaceutica	own	R23979	
34-2	Chromosomal aberration (SCK86/02D)	40729302	Janssen Pharmaceutica	own	R23979	
84-2	Chromosomal aberration (SCK86/02D - Phase 3 summar	41026602	Janssen Pharmaceutica	own	NA	
34-2	Gene Mutation (3470)	43735003	Janssen Pharmaceutica	own	R23979	
34-4	Other genotoxic effects (micronucleus-mice, 1911)	40729303	Janssen Pharmaceutica	own	R23979	
34-4	Other genotoxic effects (UDS-1, 920, rat)	43780201	Janssen Pharmaceutica	own	R23979	
34-4	Other genotoxic effects (UDS-2, 3666, mouse)	43965702	Janssen Pharmaceutica	own	R23979	
4-2	Gene mutation (Drosophila recessive lethal, 1146)	00162410	Janssen Pharmaceutica	own	R23979	
34-4	Other genotoxic effects (micronucleus-rat, 916)	00031599	Janssen Pharmaceutica	own	R23979	
				T		
Signature	11		Name and Title		Cale	
Signature William R.	Loodering		William. R. Goodwine, Director, Regulatory Affairs		May 17, 2011	



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Applicant's/Registrant's Name & Address Janssen PMP, A Division of Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, NJ 0856		J 08560-0200	Product Fungaflor Technical		
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
85-1	General metabolism-rat (FK1116)	42012003	Janssen Pharmaceutica	own	R23979
85-1	General metabolism-rat (FK1116, supplement)	43016803	Janssen Pharmaceutica	own	R23979
na Special study	Metabolism-rat (FK675, compare salts & base)	43402601	Janssen Pharmaceutica	own	R23979/R27180
na Special study	Metabolism- (Imazalil & sulfite availability)	43437401	Janssen Pharmaceutica	own	Lit.erature review
85-2	Dermal penetration (FK1326)	42913401	Janssen Pharmaceutica	own	R23979/500EC
na	Safety assessment-mice (PPD-4, liver tumors)	43202401	Janssen Pharmaceutica	own	NA
na	Safety assessment-mice (PPD-4, supplement)	43735001	Janssen Pharmaceutica	own	NA
na	Safety assessment-mice (PPD-4, supplement)	43965703	Janssen Pharmaceutica	own	NA
na	Safety assessment-(chronic/cancer risk assessment)	44269601	Janssen Pharmaceutica	own	NA
na	Safety assessment (97002?IMZ, dietary risk assessment)	44216801	Janssen Pharmaceutica	own	NA
na	Safety assessment 99023/IMA, acute/chronic diet risk +n	44858002	Janssen Pharmaceutica	owr.	NA
na	Safety assessment (9805/IMA, acute/chronic diet risk)	44567804	Janssen Pharmaceutica	own	NA
na	FQPA Supplemental Information	44567805	Janssen Pharmaceutica	own	NA.
na	Occupational Exposure Assessment (citrus/cereals)	45059601	Janssen Pharmaceutica	own	NA
na	Acute/chronic drinking water assessment (acute/chronic v	45059602	Janssen Pharmaceutica	own	MA
Signature William R. Moderne			Name and Title William R. Goodwine, Director, Regulatory Aff	airs	Cale May 17, 2011



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		Product Fungaflor Technical			
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
na -Special testing	Mechanistic-rat (5009 interim)	44951003	Janssen Pharmaceutica	own	R23979
na -Special testing	Mechanistic-rat (5009-final)	45160101	Janssen Pharmaceutica	own	R23979
na -Special testing	Mechanistic-rat (5009-addenda FK3378)	45376801	Janssen Pharmaceutica	own	R23979
na -Special testing	Mechanistic-mouse (3140-PCNA supplement)	45362601	Janssen Pharmaceutica	own	R23979
na -Special testing	Mechanistic-rat (5009-PCNA supplement)	45362602	Janssen Pharmaceutica	own	R23979
na-Special testing	Mechanistic-mouse (3140-final)	43222601	Janssen Pharmaceutica	own	R23979
na-Special testing	Mechanistic-mouse (3140-interim)	43032701	Janssen Pharmaceutica	own	R23979
na-Special Testing	Mechanistic-mouse (3140-FK1600 supplement)	43202402	Janssen Pharmaceutica	own	R23979
na-Special Testing	Mechanistic-mouse (3140-supplement)	43242402	Janssen Pharmaceutica	own	R23979
na-Special Testing	Mechanistic-mouse (WIL-43601, interim)	45708401	Janssen Pharmaceutica	own	R25979
na-Special Testing	Mechanistic-mouse (WIL-43601, final)	45713701	Janssen Pharmaceutica	OWit	R23979
na-Special Testing	Mechanistic-mouse (WIL-43601, addenda)	45783801	Janssen Pharmaceutica	oʻvn	R23979
na-Special Testing	Mechanistic-mouse (WIL-43601, addenda-PCNA)	45785601	Janssen Pharmaceutica	own	R23979
na-Special Testing	Mechanistic-mouse ((MOA overview)	45822502	Janssen Pharmaceutica	ov√n	R23979
na-Special Testing	Mechanistic-mouse (WIL-43601, addenda II)	45822503	Janssen Pharmaceutica	own	R23979
			Name and Title William. R. Goodwine, Director, Regulatory Af	fairs	Dute May 17, 2011



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		Product Fungaflor Technical			
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
161-1	Hydrolysis	00115272	Jansen Pharmaceutica	own	
161-1	Hydrolysis	42403102	Janssen Pharmaceutica	own	
161-2	Photolysis	40926701	Janssen Pharmaceutica	own	
161-2	Photolysis	41350801	Janssen Pharmaceutica	own	
162-1	Aerobic soil metabolism	148314	Janssen Pharmaceutica	own	
162-1	Aerobic soil metabolism	158160	Janssen Pharmaceutica	own	
162-3	Anaerobic aquatic	42012004	Janssen Pharmaceutica	own	
163-1	Leaching & adsorption/desorption	00148072	Janssen Pharmaceutica	own	
163-1	Leaching & adsorption/desorption	00158160	Janssen Pharmaceutica	own	
160-5	Chemical Identity	41606106	Janssen Pharmaceutica	own	
Signature William R.	Hooderine		Name and Title William. R. Goodwine, Director, Regulator	y Affairs	Ca.e May 17, 2011



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			Ingredient Imazalil		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
71-1	Avian oral LD50 - quail	00163243	Janssen Pharmaceutica	own	
71-2	Avian dietary LC50 - duck	00030542	Janssen Pharmaceutica	own	
71-2	Avian dietary LC50 - quail	00030543	Janssen Pharmaceutica	own	
71-4	Avian reproduction - duck	42039801	Janssen Pharmaceutica	own	
71-4	Avian reproduction - quail	41663801	Janssen Pharmaceutica	own	
72-1	Freshwater fish LC50	41606101	Janssen Pharmaceutica	own	
72-1	Freshwater fish LC50	41606102	Janssen Pharmaceutica	own	
72-2	Acute LC50 - freshwater invertebrates	41606103	Janssen Pharmaceutica	own	
na	Equivalency of base & salt	00146710	Janssen Pharmaceutica	own	
850.4400	Aquatic Plant toxicity Test	46818201	Janssen Pharmaceutica	own	
850.5400	Algal Toxicity Test	46818202	Janssen Pharmaceutica	OWil	
					1
Signature			Name and Title		Date
Signature William R. Lloodwinl		William. R. Goodwine, Director, Regulatory Affairs		May 17, 2011	



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Janssen PMP, a Division of Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, NJ 08560-0200			Fungaflor Technical			
Ingredient Imazalil						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
171-2	Chemical identity	40478201	Janssen Pharmaceutica	own		
171-2	Chemical identity	41545101	Janssen Pharmaceutica	own		
171-2	Chemical identity	41595901	Janssen Pharmaceutica	own		
171-2	Chemical identity	42403101	Janssen Pharmaceutica	own		
171-2	Chemical identity	43016801	Janssen Pharmaceutica	own		
171-2	Chemical identity	43223001	Janssen Pharmaceutica	own		
171-4(a)	Nature of Residue - citrus	42012008	Janssen Pharmaceutica	own		
171-49a)	Nature of Residue - citrus	42403102	Janssen Pharmaceutica	own		
171-4(a)	Nature of Residue - citrus	43308401	Janssen Pharmaceutica	own		
171-4(a)	Nature of Residue - citrus	92072037	Janssen Pharmaceutica	own		
171-4(a)	Nature of Residue - bananas	42012009	Janssen Pharmaceutica	OWI		
171-4(a)	Nature of Residue - bananas	43965701	Janssen Pharmaceutica	o\~n		
171-4(a)	Nature of Residue - wheat	42626901	Janssen Pharmaceutica	own		
171-4(a)	Nature of Residue - apples	00145199	Janssen Pharmaceutica	own		
171-4(a)	Nature of Residue - apples	00157188	Janssen Pharmaceutica	own		
Signature William R. Loodwinl		Name and Title William. R. Goodwine, Director, Regulatory Affairs		Date May 17, 2011		



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Date May 17, 2011 Applicant's/Registrant's Name & Address Janssen PMP, Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, NJ 08560-0200			EPA Reg No./File Symbol 43813-2		Page 150f 18
			Product Fungaflor Technical		
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(b)	Nature of Residue - Livestock	42454801	Janssen Pharmaceutica	own	
171-4(b)	Nature of Residue - Livestock	42454802	Janssen Pharmaceutica	own	
171-4(b)	Nature of Residue - Livestock	42593602	Janssen Pharmaceutica	own	
171-4(b)	Nature of Residue - Livestock	42838201	Janssen Pharmaceutica	own	
171-4(b)	Nature of Residue - Poultry	00148884	Janssen Pharmaceutica	own	
171-4(b)	Nature of Residue - Poultry	43076101	Janssen Pharmaceutica	own	
171-4(c)	Residue Analytical Method - citrus	00109269	Janssen Pharmaceutica	own	
171-4(c)	Residue Analytical Method - citrus	42454804	Janssen Pharmaceutica	own	
171-4(c)	Residue Analytical Method - bananas	42454803	Janssen Pharmaceutica	own	
171-4(c)	Residue Analytical Method - bananas	42454805	Janssen Pharmaceutica	own	
171-4(c)	Residue Analytical Method - cereals	42626902	Janssen Pharmaceutica	OWII	
171-4(c)	Residue Analytical Method - Radiovalidation	44532901	Janssen Pharmaceutica	O'YN	
71-4(d)	Residue Analytical Method - poultry (feasibility)	44786501	Janssen Pharmaceutica	own	
171-4(d)	Residue Analytical Method - poultry (validation)	44858003	Janssen Pharmaceutica	ov₊n	
Signature]	Name and Title		ı)ate
William R. Moodwine			William. R. Goodwine, Director, Regulatory Affairs		May 17, 2011



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Applicant's/Registrant's Name & Ac			Product			
Janssen PMP, a Division of Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, NJ 085			Fungaflor Technical			
Ingredient Imazalil						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
171-4(d)	Residue Analytical method - livestock	00109269	Janssen Pharmaceutica	own		
171-4(d)	Residue Analytical method - livestock (feasibility)	44051701	Janssen Pharmaceutica	own		
171-4(d)	Residue Analytical method - livestock (feasibility)	44337701	Janssen Pharmaceutica	own		
171-4(d)	Residue Analytical method - livestock (validation)	44455601	Janssen Pharmaceutica	own		
171-4	Residue Analytical Method - Multi-residue (AGR345)	45520401	Janssen Pharmaceutica	own		
171-4(e)	Storage stability - citrus	42643301	Janssen Pharmaceutica	own		
171-4(e)	Storage stability - bananas	42626903	Janssen Pharmaceutica	own		
71-4(e)	Storage stability - cereals	00157189	Janssen Pharmaceutica	own		
171-4(e)	Storage stability - cereals	42755301	Janssen Pharmaceutica	own		
171-4 (d)	Residue Analytical method - livestock (AGR361, validatio	45589501	Janssen Pharmaceutica	own		
171-4 (d)	Residue Analytical method - livestock (AGR415, ILV)	45589502	Janssen Pharmaceutica	own		
		•				
Signature William R. Moodewine			Name and Title		ı)ate	
William R.	L'oodewine		William. R. Goodwine, Director, Regulatory Affairs		May 17, 2011	



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			Product Fungaflor Technical		
Ingredient Imazalil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(j)	Magnitude of Residue - livestock	00109269	Janssen Pharmaceutica	own	
171-4(j)	Magnitude of Residue - livestock	44568301	Janssen Pharmaceutica	own	
171-4(j)	Magnitude of Residue - poultry	44918801	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - citrus	40509402	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - citrus	40509403	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - citrus	40713805	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - citrus	92072040	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - bananas	42058701	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - bananas	42454805	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - bananas	42710501	Janssen Pharmaceutica	own	
171-4(I)	Magnitude of Residue -citrus	40509403	Janssen Pharmaceutica	OWL	
171-4(I)	Magnitude of Residue -citrus	42348301	Janssen Pharmaceutica	υwn	
171-4(I)	Magnitude of Residue -citrus	42405501	Janssen Pharmaceutica	own	
171-4(1)	Magnitude of Residue -citrus	42454806	Janssen Pharmaceutica	ov.n	
Milliam R. Mordium			Name and Title William. R. Goodwine, Director, Regulatory Affairs		Date May 17, 2011



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4(k)	Magnitude of Residue - cereals	00150020	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - cereals	00157190	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - cereals	42852001	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - cereals	42852002	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - cereals	42868101	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - cereals	43285001	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - cereals	92072041	Janssen Pharmaceutica	own	
171-4(k)	Magnitude of Residue - cereals	92072042	Janssen Pharmaceutica	own	
Signature William R. Loodiwine		Name and Title		l rate	
		William. R. Goodwine, Director, Regulatory Affairs		May 17, 2011	